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ORIGINAL ARTICLE

Role of fluoroscopic guided self expandable metallic stents in the management of malignant esophageal strictures

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KEYWORDS

Esophageal cancer;
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Abstract *Objectives:* To evaluate the role of fluoroscopic guided self expanding metallic stents in the management of dysphagia caused by malignant esophageal strictures.
Materials and methods: During the period between April 2010 and October 2012, 31 patients with malignant esophageal strictures were subjected to fluoroscopic guided self expanding metallic stent application. The study included 22 males and 9 females ranging in age between 22 and 75 years old with mean age of 56.8 years. Lesions were located in the lower esophagus and gastroesophageal junction in 22 patients and middle esophagus in 9 patients.
Results: Technical success was achieved in all 31 cases (100%). The clinical success was 96.7% with 81% mean improvement in dysphagia according to dysphagia score. Only one major complication occured (3.2%) which was proximal stent migration.
Conclusion: Fluoroscopic guided esophageal stenting is a highly effective and safe method for palliating dysphagia in patients with obstructing esophageal cancer with significant clinical improvement.

1. Introduction

The survival rates of patients with malignant esophageal obstruction are only improved by surgical resection at a very early stage (1). In more advanced stages, therapy is usually palliative in nature, the main aims being relief of dysphagia and maintenance of nutrition. Esophageal intubation with a laparotomy induced plastic endoprosthesis has been practiced for the palliation of dysphagia from malignant esophageal obstruction. Endoscopically inserted plastic prosthesis was

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introduced in the 1970s, with a much reduced complication rate. These stents had small internal diameter (10–12 mm), resulting in many patients having difficulty in resuming a normal diet. They had a relatively high complication rate (up to 36%), mainly due to esophageal perforation, with a high procedure-related mortality rate. Plastic stents have been superseded by the new metallic self-expanding stents which are considered safer and easier to place (2). The major impact of these stents relates to the ease of their insertion and the potential for few complications because of the small caliber delivery system (3).

In this study we evaluate the role of Fluoroscopic guided self expanding metallic stents in the management of dysphagia caused by malignant esophageal strictures.

2. Materials and methods

2.1. Patient population

In this retrospective study, over a period of 30 months, thirty-one patients with dysphagia caused by malignant esophageal strictures were presented to Interventional Radiology Unit, Ain Shams University hospitals, for esophageal stent application. The study included 22 males (71%) and 9 females (29%) ranging in age between 22 and 75 years old (mean = 56.8 - years). Lesions were located in the lower esophagus and gastroesophageal junction in 22 patients (71%) and middle esophagus in 9 patients (29%).

2.2. Inclusion criteria

Patients with irresectable esophageal cancer whether located at middle or lower third as well as at gastro-esophageal junction were included in the study. The treatment decision was made after multidisciplinary discussion between surgeons and interventional radiologists on the basis of clinical and radiological criteria.

2.3. Exclusion criteria

Patients with postcricoid carcinoma were excluded from the study due to the intolerable foreign body pharyngeal sensation. Patients with high bleeding profile liable for uncontrollable hemorrhage during or after the procedure were also excluded on the basis of International Normalization Ratio (INR) and platelets count; those with INR above 1.5 as well as those with platelet count less than 50,000 were excluded or postponed till correction of the bleeding profile. Patients who were not fit for general anesthesia or those with very poor general condition were excluded as well.

2.4. Patient preparation and preprocedural assessment

Full clinical and general examination was done to assess patient's general condition. All patients were subjected to full history taking with stress on severity of dysphagia, so all patients were given a score on the dysphagia score from 0 to 4 according to dysphagia scoring system, first utilized by Knyrim et al. (4), for describing the results of stent insertion as follows; 0 = able to eat normal diet/no dysphagia, 1 = able to swallow some solid foods, 2 = able to swallow only semi solid foods, 3 = able to swallow liquids only, 4 = unable to swallow anything/absolute dysphagia.

A complete blood count and bleeding profile were obtained within 24 h of the procedure. General laboratory studies routinely done prior to general anesthesia were also done to all patients. Oral contrast study was done for preprocedural assessment.

The procedure details were explained to the patients and their relatives and a written consent was signed; in which the risks of the procedure were clarified.

2.5. Technique

Two X-ray machines were used in the study: Toshiba machine Infinix INFX-8000V and Toshiba machine Max 1000, all stents were placed under general anesthesia in supine position, a nasogastric tube was introduced till the site of the obstruction, diluted water soluble contrast medium was then injected through the nasogastric tube to delineate the stricture, a hydrophilic coated 180 cm guidewire (Glidewire Terumo Medical Company TMC; Tokyo, Japan) was introduced through the stricture, after bypassing the stricture the nasogastric tube was removed and the hydrophilic guidewire was then replaced by a superstiff guidewire (Amplatz superstiff guidewire; Boston Scientific, Natick, MA, USA) through an exchange 5F Cobra catheter (Boston Scientific, Natick, MA, USA), the Cobra catheter was then removed and the stent was introduced over the stiff guidewire, the stent was then deployed after confirming good position under fluoroscopic guidance, and finally contrast medium was injected again to ensure proper function and position of the stent (Fig. 1).

Two types of partially covered self expanding nitinol stents were used in our study according to availability in market and in our unit: Ultraflex stent Boston Scientific, Natick, MA, USA which was used in 25 patients with 12–15 cm stent length and 18–23 mm stent diameter, and Choostent™ M.I. Tech. Co., Ltd. Seoul; Korea which was used in 6 patients with 12–17 cm stent length and 18 mm stent diameter.

In 5 patients balloon dilatation was needed prior to stent application due to tight strictures thus facilitating the insertion of stents, and we used the balloons as they have better radial force and less recoil compared to the dilators, and in 2 patients balloon dilatation was done after application. The balloon used was CRE Wireguided Balloon Dilator, Boston Scientific, Natick, MA, USA.

After the procedure we permitted patients to take fluids 4 h after the procedure to allow enough time to recover from anesthesia and for the rest of day, the next 6 days patients were only allowed to take semisolids. Then follow-up esophagography was done 1 week after the procedure, if totally patent lumen patients could take solid foods yet instructed to chew food extensively to decrease the risk of stent obstruction. In gastroesophageal junction tumors which was the majority of our cases, *Ranitidine*; *Zantac* once daily at night and *Domperidone; Motinorm* 15 min before each meal were prescribed to reduce gastroesophageal reflux through the stent. Then we followed up the patients on monthly basis assessing the dysphagia score.

Then we followed up the patients on monthly basis assessing the dysphagia score for describing the results of stent

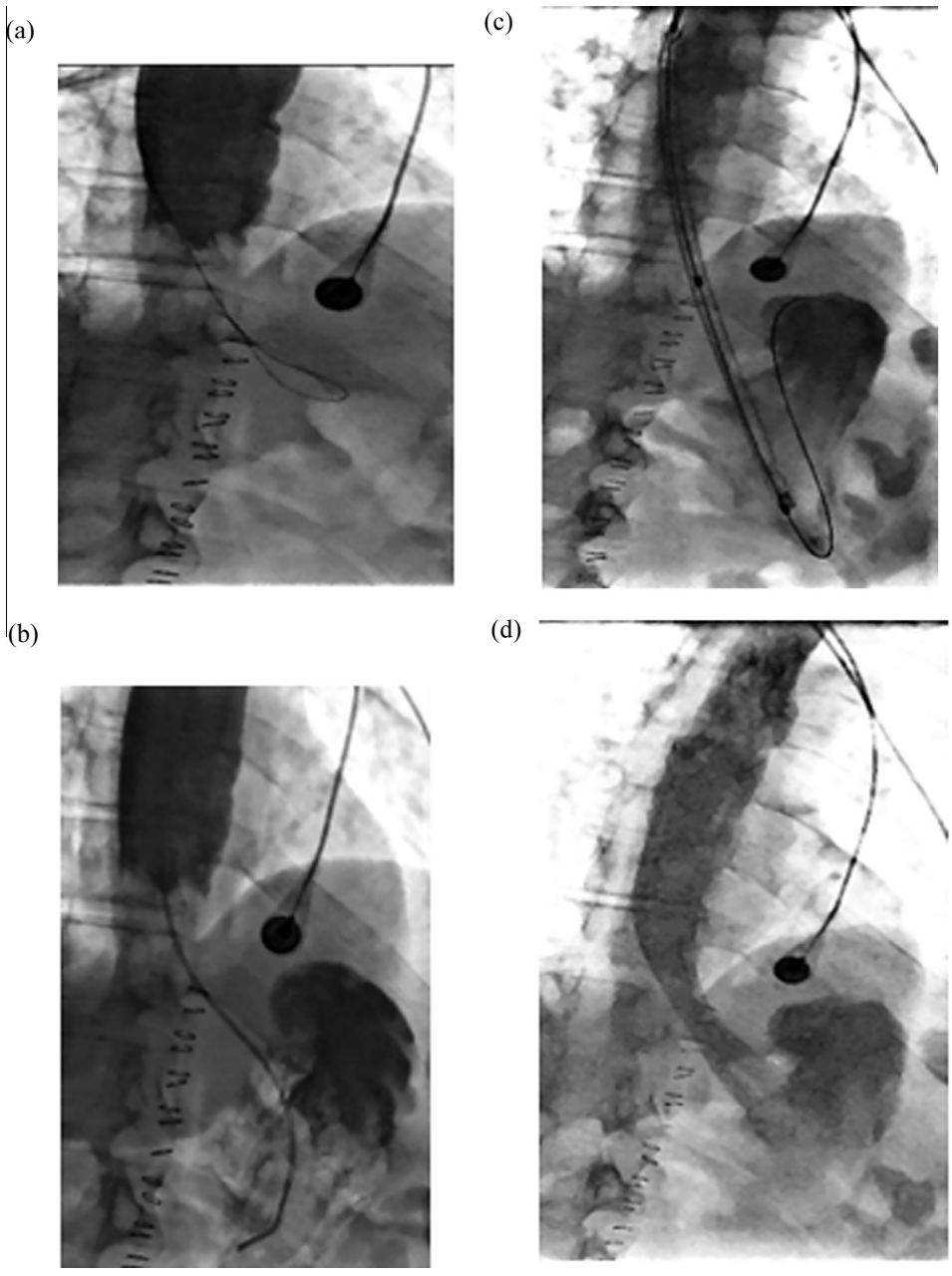

Fig. 1 Showing steps of stent insertion: (a) a water soluble contrast medium is injected to delineate the obstruction and then a hydrophilic guidewire is introduced across the stricture into the stomach. (b) A Cobra catheter is introduced into the stomach over the hydrophilic guidewire which is removed to be replaced by a superstiff guidewire. (c) Stent introduced over a superstiff guidewire. (d) Stent after deployment with final esophagogram.

insertion as follows; 0 = able to eat normal diet/no dysphagia. 1 = able to swallow some solid foods 2 = able to swallow only semi solid foods 3 = able to swallow liquids only 4 = unable to swallow anything/absolute dysphagia. If patient reported any difficulty or vomiting, we did a follow-up esophagography to reassess stent position and function, however there were no recorded stent stenosis in the followed patients and no significant esophagography findings. We could follow up 21 patients till death.

2.6. Data analysis and statistics

Technical success rate was defined as successful application of the stent across the stricture with free flow of contrast from esophagus to the stomach. Clinical success was defined as improvement in dysphagia at least 1 level up on the dysphagia score. This was evaluated subjectively by the patient and by barium swallow. Complications were defined as major (aspira-

tion, bleeding, stent migration, perforation) or minor (reflux esophagitis, chest pain, pharyngeal discomfort).

Analysis of data was done by IBM computer using SPSS (statistical program for social science version 12) as follows. Description of quantitative variables as mean, SD and range; description of qualitative variables as number and percentage; Chi-square test was used to compare qualitative variables between groups, and Paired *t*-test was used for comparison of quantities variables, in parametric data (SD < 50%) of mean in the same group.

P value

P value > 0.05 insignificant

P < 0.05 significant

P < 0.01 highly significant (5)

3. Results

We achieved 100% technical success rate with proper positioning of the stent across the obstructed segment and restoring esophageal patency.

Concerning clinical success it was evaluated subjectively 1 week after the procedure according to the dysphagia score. One patient was admitted to the ICU few days after the procedure due to severe chest infection and died 1 week later, so clinical result of stent insertion could not be properly evaluated in this patient, while all other patients recorded improvement in swallowing, so clinical success rate was considered 96.7% with 81% mean improvement in dysphagia according to dysphagia score.

Twenty-four patients were presented with dysphagia score 4, 5 patients with score 3 and 2 patients with score 2 with mean dysphagia score of 3.7 which was improved to a mean grade of 0.74 after stent placement (Table 1). Thirteen patients improved to dysphagia score 0, 11 patients to score 1, and 6 patients to score 2 within 1 week after the procedure (Fig. 2).

Concerning complications, we faced one major complication (3.2%) which is proximal stent migration 24 h after application due to an attack of severe cough, another stent was overlapped through the migrated stent reopening the stricture and clinical success was evaluated after application of the second stent (Fig. 3).

We did not consider the patient who died in ICU from chest infection to be a complication because the mortality cause was not procedure related. Minor bleeding occurred in 4 patients in our study (12.9%); it was self limited and needed no further management. No procedure related mortality. Twenty-one patients were followed up till death and their life span ranged between 10 days and 56 weeks with mean of 25 weeks and stents remained functioning till death in these patients, while 10 patients were lost during follow-up.

Table 1 Pre- and postprocedural dysphagia score mean and SD.

	Mean	±SD	% of change	*t*	*P*
Pre	3.7	0.5	81%	18	<0.001
Post	0.77	0.3			HS

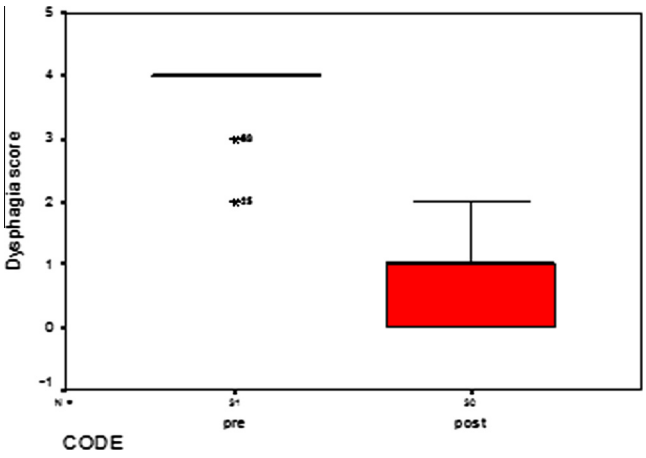

Fig. 2 Box plot of dysphagia score comparison pre- and postprocedural showing significant improvement of dysphagia score poststenting.

4. Discussion

Esophageal cancer is often irresectable at the time of its diagnosis due to either local invasion or metastatic disease. The main goals of therapy, which is usually palliative, are relief of dysphagia with maintenance of nutrition and occlusion of trachea-esophageal fistulas (3).

Although palliative surgery used to be an accepted method to restore swallowing, most patients are in generally bad health with a short life expectancy, thus forbidding surgical palliation. Several reports have been published on various other palliative treatment methods. Pros and cons of chemotherapy, radiation, application of laser beams; however, none of these therapies is entirely satisfactory (6).

Palliation of malignant dysphagia in patients with esophageal cancer or gastric cardiac cancer is the most common indication for placement of esophageal self expanding metal stents (SEMS). These patients are judged to be inoperable because of extensive local or regional disease or poor general status because of advanced age, co-morbidity, or both.

There is no current consensus on absolute contraindications for esophageal SEMS placement, but it is of utmost importance to carefully select the patients. Patients with multiple metastases, short life expectancy (less than 4 weeks) or peritoneal seeding should not be considered as candidates. Patients with high bleeding tendency who are liable for uncontrollable hemorrhage should be also excluded (3).

Various esophageal self-expanding metal stents (SEMSs) have recently been developed for palliative treatment of malignant obstruction of the gastrointestinal tracts. The major impact of these metallic stents is related to the ease of its insertion and the potential for less complications compared with plastic stents (3).

Stents are available in 3 types: uncovered, fully covered, and partially covered. The original esophageal SEMS were uncovered, with no synthetic material covering the metal mesh. However, a variety of covering materials (most commonly polytetrafluoroethylene) have been developed due to complications of tumor and granulation tissue ingrowth. Fully covered stents do not have any exposed bare metal, but they are more

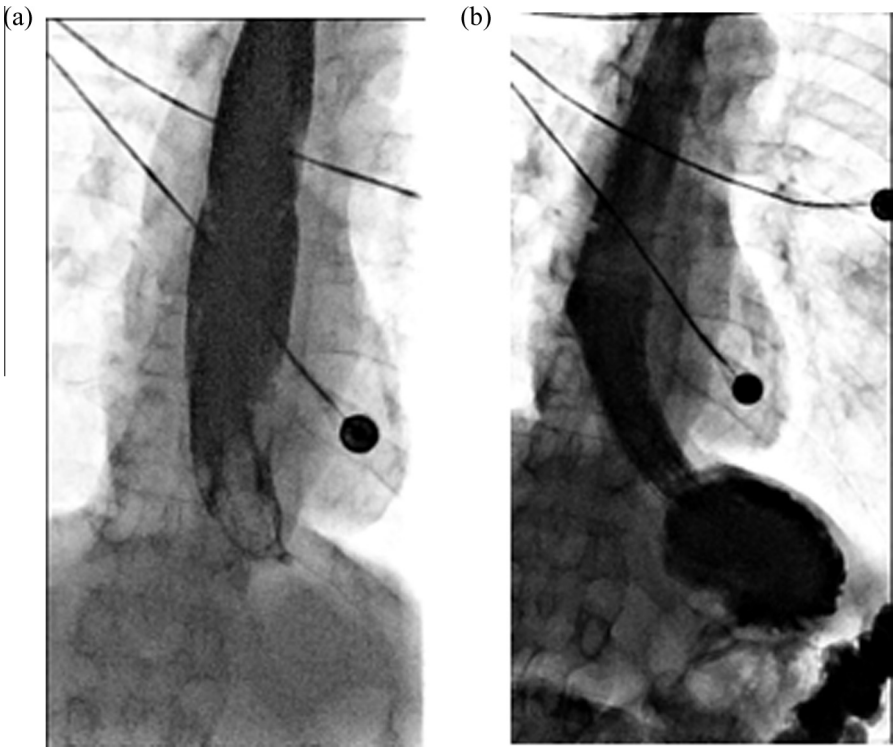

Fig. 3 (a) Inserted first stent is migrated above the stricture with no passage of contrast into the stomach (b) After insertion of another stent passing through the stricture with free passage of contrast into the stomach.

prone to stent migration. Partially covered SEMS have a small portion of exposed bare metal at the proximal and distal ends to allow embedding into the esophageal wall, which helps to prevent migration (7).

In an attempt to remedy the problem of reflux in distal esophageal stricture after stenting, stents with antireflux mechanisms have been developed as Cook Medical's Esophageal Z-Stent with Dua Anti-Reflux Valve (8).

SEMS have been shown to be safer and more cost-effective than self-expandable plastic stents (SESP) used previously. SEMS had a much lower complication rate than SEPS (9% vs 22%, respectively). SEPS are used mainly for management of benign esophageal strictures (9).

Biodegradable stents have recently been developed in the hopes of avoiding the complications of tissue ingrowth and migration and decreasing the need for reinterventions for stent removal. Preliminary data show that these stents may provide a valuable alternative to plastic and metal stents and may eliminate the need for repeat esophageal dilations. However, biodegradable stents may also present new challenges, and further studies are necessary (10).

In our study a 100% technical success rate was achieved with proper positioning of the stent and successful restoration of patency of the esophageal lumen in all patients. We used the nasogastric tube to access the esophagus as it is less invasive than the endoscope, also the use of nasogastric tube can be done in supine position not in prone position like the endoscope and prone position is more risky than the endoscope during anesthesia and while the endoscope has the ability to visualize directly the site of obstruction, we can delineate the site of obstruction using the nasogastric tube with contrast injection.

Many authors reported a technical success rate of 100% with fluoroscopic guidance (11–15), while Cwikiel et al. (16) achieved 97% technical success. Saxon and his colleagues (17) carried out this on 52 patients with 96% technical success.

Clinical success was defined as improvement in dysphagia by at least 1 level up on the dysphagia score. This definition was applied in most of the published series. It was 100% in Robert and Andy (12) series with decrease in mean dysphagia score from 3 to 1. O'Sullivan and his co-authors (11) reported 95% clinical success. Tanaka et al. (13) who used partially covered SEMS as in our study adopted another approach to assess clinical success which was food intake score which is the opposite of dysphagia score (0 = complete dysphagia, 1 = liquids only, 2 = semisolids, 3 = some solid food, 4 = normal diet). Food intake score, which was 1 ± 0.7 (mean ± SD) before stent placement, improved to 3.1 ± 1.3 after stent placement. This study reported 20% clinical failure in which dysphagia was not relieved (8 patients) but the study explained this by the very poor clinical condition of the patients as 6 of those 8 patients died from poor general condition for various reasons within 4 weeks post-stenting. In our study, we used the dysphagia score system.

As for the aftercare of the patients, similar studies (11–13) described nearly similar aftercare steps as that adopted in our study; in which we permitted patients to take fluids 4 h after the procedure to allow enough time to recover from anesthesia and for the rest of day. The next 6 days; patients were only allowed to take semisolids. Then follow-up esophagography was done 1 week after the procedure, if totally patent lumen patients could take solid foods yet instructed to chew food extensively to decrease the risk of stent obstruction. In gastroesophageal junction tumors which was the majority of our cases

Ranitidine; Zantac once daily at night and *Domperidone*; *Motinorm* 15 min before each meal were prescribed to reduce gastroesophageal reflux through the stent.

Concerning complications; in one patient the stent migrated proximally 24 h after application due to an attack of severe cough, another stent was overlapped through the migrated stent reopening the stricture. Minor bleeding occurred in 4 patients in our study. No perforation occurred. No aspiration occurred. In addition, no tumor ingrowth occurred as we only used covered stents. Most of the patients reported mild chest pain which was more obvious in patients with gastroesophageal junction tumors but needed no specific management. Pharyngeal discomfort postprocedure was common as well for the first few days.

Tanaka et al. (13) described complications as follows; stent migration (occurred in one patient), massive hemorrhage (occurred in four patients), food impaction (in one patient) and pneumonia (in one patient). Minor hemorrhage occurred in two patients. Aspiration pneumonia developed in one patient with recurrent esophageal cancer after radiotherapy. Robert and Andy (12) reported migration as the main complication of covered stents; this is particularly common in distal esophageal lesions involving the gastro-esophageal junction, which was 22% in this study. They mentioned the main complication of uncovered stents is tumor ingrowth and overgrowth, which occurs in 17–36% of cases. Covered stents are resistant to ingrowth but may occlude secondary to overgrowth in as many as 9% of cases. They concluded that hemorrhage either procedural or late hemorrhage is uncommon, and is usually mild and self-limiting. However, severe hemorrhage can occur in as many as 6% of patients and this may be related to erosion of esophageal vessels by the stent or to local tumor invasion. O'Sullivan and Alan (11) reported that most patients have slight discomfort on initial insertion of the stent; in their series. Two patients had minor bleeding; more serious bleeding is rare; in one patient erosion of the proximal end of a stent through the esophageal lumen and subsequently into the aorta occurred with fatal hemorrhage. A further patient required radiation therapy to diminish persistent mild hemorrhage after insertion of a stent.

Tanaka et al. (13) reported the death of 4 patients of massive hemorrhage but all of them were referred for stenting after radiation therapy. O'Sullivan and his colleagues (11) reported that; although fatal bleeding occurred in one of their patients, this is quite rare and occurred on a background of previous radiation therapy. The study done by Robert and Andy (12) did not report causes of death in his study.

In our study; 21 patients died between 10 days and 56 weeks postprocedure from various conditions mostly metastasis or co-morbidity but the exact causes were not very clear in most of patients as we were reported by the deaths by phone calls to the relatives and were reported retrospectively.

We had a number of limitations in our study, many patients were lost in the follow-up; causes of death could not be clarified in other patients as they were not admitted to the hospital at time of death. Financial issues hindered us form trying antireflux and antimigration stents yet migration was only seen in one patient in our study and was proximal not distal migration.

In conclusion, fluoroscopic guided esophageal stenting is a highly efficient and safe tool of palliation of severe dysphagia secondary to obstructing esophageal cancer with significant improvement of dysphagia score.

Conflict of interest

The authors declare that there is no conflict of interest.

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